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Date: March 8, 2004

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Mr. Jon Clark
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville MD 20852

Docket No: 03-28045

Re: FDA Draft Guidance for Industry: Powder Blends and Finished Dosage Units -

Stratified In-Process Dosage Unit Sampling and Assessment

Dear Mr. Clark:

The above referenced FDA draft guidance entitled Powder Blends and Finished Dosage Units – Stratified In-Process Dosage Unit Sampling and Assessment, issued October 2003 has been reviewed by scientists at Johnson & Johnson Pharmaceutical Research and Development, LLC and Johnson & Johnson affiliates. The following comments represent the general impressions of our scientists concerning issues of great importance to our business.

General Discussion:

Scientists from various functional groups within our organization closely reviewed and discussed the implications of the draft guidance proposals to development products, newly approved products and established marketed products. Despite much debate, the group recognizes FDA's motivation to create a consistent approach regarding the GMP requirements for blend uniformity testing. Further, our scientists recognize the guidance recommendations as a furtherance of FDA's science-based manufacturing and PAT initiative. The group has no objection to the proposed recommendations for drug products in development and newly approved drugs and believes it will bring positive outcomes for both pharmaceutical manufactures and customers.

Our scientists are primarily concerned about the implications of the draft guidance recommendations to established marketed products and request that the draft guidance clearly state whether or not the draft guidance applies to established marketed products. We believe that the stratified sampling and powder blend uniformity testing recommendations should not apply to established marketed products. Application of these additional requirements would impose an unreasonable burden (sample handling and shifting batch-testing criteria logistics) upon proprietary pharmaceutical manufacturers for established marketed products where out-of-specification results are few and considerable historic data already exist.





Rather than impose the new requirements for all drug products, we believe a compromise approach should be adopted. Under this approach, the requirement for stratified sampling and powder blend uniformity testing would apply to development and newly approved drug products but not to established marketed products if the integrity of the manufacturing process and drug product can be demonstrated by historic data. We believe this approach supports FDA's goal to establish a consistent approach to GMP blend uniformity and the furtherance of science-based manufacturing and PAT initiative.

We greatly appreciate the opportunity to comment on this draft guidance and look forward to working closely with FDA on future documents. If you have questions or need assistance, please contact me directly at 609/730-3425.

Sincerely, Sue Halley

Manager

Global Chem-Pharm Regulatory Sciences

Johnson & Johnson Pharmaceutical Research and Development, LLC.